



OSTI-LBNL ORGANIZATIONAL STRUCTURE

QA: QA

*Quality Implementing Procedure ID: OSTI-LBNL-QIP-1.0, Rev.0, Mod.1**Effective: 04/21/04*

1. PURPOSE

This Quality Implementing Procedure (QIP) describes the organizational structure, functional responsibilities, levels of authority, and lines of communication between the U.S. Department of Energy (DOE) Office of Civilian Radioactive Waste Management (OCRWM) Office of Science & Technology and International (OSTI) and Lawrence Berkeley National Laboratory (LBNL). The OSTI-LBNL Quality Assurance (QA) Program has been established for application on OSTI-LBNL Project activities. The procedure also identifies the interface between the OSTI-LBNL QA organization and the DOE Office of Quality Assurance (OQA), and the independent reporting structure for QA responsibilities.

2. SCOPE

This procedure is applicable to the organizations and personnel directly responsible for establishing and executing work assignments supporting OSTI-LBNL activities. This procedure describes the overall responsibilities of the OSTI-LBNL organization to meet the requirements of the DOE OCRWM *Quality Assurance Requirements and Description* (QARD), DOE/RW-0333P, as described in the *OSTI-LBNL QA Plan* and detailed responsibility descriptions defined in OSTI-LBNL-QIPs and OSTI-LBNL-Technical Implementing Procedures (TIPs).

3. PROCEDURE

3.1 Changes to Procedure

The Project Manager (PM) for the OSTI-LBNL Project shall direct the OSTI-LBNL QA Manager to revise this QIP based on DOE or LBNL changes to the organization responsibilities described in Sections 3.4, 3.5 and 3.6 of this procedure. Changes shall be prepared in accordance with the OSTI-LBNL-QIP-5.0, *Preparing the Quality Assurance Plan and Quality/Technical Implementing Procedures*. Reviews shall be performed in accordance with OSTI-LBNL-QIP-6.1, *Document Review*.

3.2 Assignment of Work and Delegation of Authority

The PM retains responsibility for overall implementation of the OSTI-LBNL QA Program. The PM has assigned responsibilities and delegated authority to key OSTI-LBNL staff members as described in Sections 3.4, 3.5, and 3.6 below. Detailed responsibilities for OSTI-LBNL activities are described in applicable OSTI-LBNL Technical Work Plans (TWP), OSTI-LBNL-QIPs, and OSTI-LBNL-TIPs. OSTI-LBNL TWPs and implementing procedures are reviewed and approved by the PM.

Positions or organizations responsible for establishing and executing the quality program may delegate work and/or signature authority to other positions or organizations. Such delegation shall be made in writing (e.g., interoffice

correspondence, electronic mail, or letter), except in those cases where "or designee" is stated within a QIP or TIP. The positions or organizations making the delegation shall identify the beginning and end dates of the delegation, and shall retain overall responsibility for the delegated work. Documented delegation of authority shall be transmitted to the OSTI-LBNL Records Coordinator for submittal to the Records Processing Center (RPC) in Las Vegas in accordance with OSTI-LBNL-QIP-17.0, *Record Management*. As an alternative, if delegation is documented by electronic mail via Lotus Notes, the e-mail may be classified as a QA/inclusionary document, in which case the e-mail will automatically be submitted by Lotus Notes to the RPC.

3.3 Resolution of Quality Disputes

Conflicts or disputes involving quality or technical issues arising from a difference of opinion between OSTI-LBNL personnel shall be referred to successively higher levels of management within LBNL and ultimately be resolved by the PM or designee. Quality-related disputes involving OSTI-LBNL personnel, and OCRWM OQA personnel that cannot be resolved shall be referred to successively higher levels of management within the OSTI-LBNL Project. If satisfactory resolution cannot be obtained at that level, the dispute shall be submitted to OCRWM for resolution.

3.4 OSTI-LBNL Organizational Relationships, Responsibilities, and Interface with DOE/OCRWM Quality Assurance Organization

The OSTI-LBNL Project is executed within the LBNL Earth Sciences Division (ESD), as part of the Nuclear Waste Program (NWP). The organizational structure of the OSTI-LBNL Project and the relationship with OCRWM OQA and OSTI is shown in Attachment 1, OSTI-LBNL Organizational Structure.

Overall responsibilities for key OSTI-LBNL staff members are described in this Section, and in Sections 3.5 and 3.6 below. Detailed responsibilities are described in OSTI-LBNL QA implementing procedures. Throughout the program, quality shall be achieved and maintained by those who have been assigned responsibility for performing the work. Quality achievement shall be verified by persons or organizations not directly responsible for performing the work.

3.4.1 Program Manager, Nuclear Waste Program (Project Manager)

The LBNL Director of ESD has the overall responsibility for the management of the OSTI-LBNL Project. The ESD Director delegates the responsibility and authority for the OSTI-LBNL Project to the ESD NWP Manager, who hereafter is referred to as Project Manager (PM) throughout the OSTI-LBNL-QA Program. The PM reports to the ESD Director, and has overall responsibility for ensuring the achievement and maintenance of quality on the OSTI-LBNL Project. The line of communication between the PM and OCRWM is through the DOE Technical Task Representative and the OQA representative. The PM shall issue and maintain a policy statement directing mandatory compliance with the OSTI-LBNL QA Program documents by

OSTI-LBNL personnel. Specific responsibilities of the PM include, but are not limited to:

- A. managing the OSTI-LBNL technical work subject to the OSTI-LBNL QA Program, and ensuring implementation thereof.
- B. authorizing the establishment of and approving the *OSTI-LBNL QA Plan*, and implementing procedure documents;
- C. providing overall direction for project planning and assigning technical work;
- D. providing final resolution on conflicts or disputes within OSTI-LBNL involving quality; for quality-related disputes between organizations, providing final resolution on conflicts together with the Director, OQA, as applicable.
- E. ensuring OSTI-LBNL staff are adequately trained to OSTI-LBNL QA Program requirements to ensure the highest quality work products.
- F. interfacing with the Principal Investigators (PIs) and the OSTI-LBNL QA Manager to ensure quality matters are adequately addressed.
- G. keeping the DOE Technical Task Representative apprized of work progress.

3.4.2 Deputy Project Manager

The Deputy PM reports to the PM, and has responsibility for oversight of the NWP QA Technical Support Staff, for assigning qualified Checkers, Technical and QA Reviewers to review scientific documents, and for other tasks as delegated by the PM.

3.5 LBNL Nuclear Waste Program Quality Assurance Technical Support

The OSTI-LBNL QA Manager and QA technical support staff are a part of the Technical and Administrative Support Department within ESD and report to the Deputy PM on the OSTI-LBNL Project. QA staff under the direction of the Deputy PM and the QA Manager, work in collaboration with the PIs and scientific staff to ensure the implementation of the *OSTI-LBNL QA Plan* and OSTI-LBNL QA implementing procedures. QA staff members are responsible for assisting in the integration of quality requirements into technical activities. QA staff, together with line technical staff, are responsible for identifying problems relating to quality and for working with other technical/administrative personnel to define and implement solutions to problems.

3.5.1 Quality Assurance Manager

The PM shall designate a QA Manager for the OSTI-LBNL Project who has appropriate knowledge and experience in management and QA. The OSTI-LBNL QA Manager is responsible for directing the implementation of the OSTI-LBNL QA Program for application on the OSTI-LBNL Project. The QA Manager position is at the same or higher organizational level as the PIs on the OSTI-LBNL Project. The QA Manager interfaces with project personnel on quality matters as necessary, and will refer any quality-related unresolved conflicts and disputes to the Deputy PM for further resolution, and if needed, to successively higher levels of management as described in Section 3.3. The responsibilities of the OSTI-LBNL QA Manager include, but are not limited to:

- A. being sufficiently independent from cost and scheduling considerations and have the organizational freedom to communicate to all levels about QA matters;
- B. communicating regularly with the PM, and Deputy PM regarding the effectiveness and adequacy of the OSTI-LBNL QA Program, and serve as primary liaison with the DOE/OQA Representative on QA matters;
- C. having the responsibility and authority to coordinate the OSTI-LBNL QA Program to ensure the development, implementation, and maintenance thereof; being responsible for reviewing, interpreting, and approving the OSTI-LBNL QA procedures to assure they meet LBNL and DOE QA requirements; directing the accomplishment of QA program training thereof;
- D. having no other assigned responsibilities unrelated to LBNL QA Programs that would prevent full attention to QA matters;
- E. identifying quality problems, initiating, recommending, or providing solutions to quality problems; initiating, preparing/coordinating responses to Conditions Adverse to Quality (CAQ) and verify the disposition, including stopping work when it has been determined that conditions warrant this; resolving difference relative to quality matters, escalating them to the Deputy PM or the PM, as necessary.
- F. overseeing the proper establishment and implementation of the OSTI-LBNL QA Program, reporting QA program information to management, QA staff, and other affected organizations as appropriate; overseeing software, scientific notebook, records coordination, OSTI-LBNL training activities, and all QA support functions overall;

- G. reviewing changes to the QARD and revising OSTI-LBNL QA Program documents as applicable; identifying where within the OSTI-LBNL QA Program QARD requirements are met, noting applicability and exceptions to requirements, and including justification thereof; working with PIs to establish TIPs, ensuring imposed QA requirements are met.
- H. coordinating with OQA the plan, schedule, and conduct of OQA QA audits that verify the execution of the QA Program;
- I. together with the Deputy PM, identifying surveillances to be performed, and conducting internal surveillances per OSTI-LBNL-QIP-2.3, *Surveillances*.

3.5.2 Technical Data Coordinator

The Technical Data Coordinator is responsible for submitting OSTI-LBNL key data to the appropriate database within the YMP Technical Data Management System (TDMS) and for coordinating technical reviews of all data submittals in accordance with OSTI-LBNL-QIP-SIII.3, *Submittal and Incorporation of Data to the Technical Data Management System*.

3.5.3 Procurement Coordinator

The Procurement Coordinator is responsible for coordinating procurement activities between OSTI-LBNL staff requesting quality-affecting services and procurements in accordance with OSTI-LBNL-QIP-4.0, *Procurement Document Control* and OSTI-LBNL-QIP-7.0, *Control of Purchased Services*.

3.5.4 Software Coordinator

The Software Coordinator is responsible for providing software configuration management control and coordinating activities between OSTI-LBNL staff in accordance with OSTI-LBNL-SI.0, *Software Management*. The Software Coordinator works with the developers and users of software on OSTI-LBNL quality-affecting work to ensure the development and installation processes proceed according to the OSTI-LBNL QA Program and technical requirements for software.

3.5.5 Training Coordinator

The Training Coordinator, based on input from the Deputy PM, the QA Manager, or PI, is responsible for ensuring that OSTI-LBNL staff have the necessary QA training, by coordinating and providing the training as deemed necessary, in accordance with OSTI-LBNL-QIP-2.0, *Indoctrination and Training of Personnel*. In addition, the Training Coordinator is responsible for ensuring that OSTI-LBNL staff have documented position descriptions and that required education and experience have been verified in accordance with

OSTI-LBNL-QIP-2.1, *Establishment and Verification of Required Education and Experience of Personnel*.

3.5.6 Scientific Notebook Coordinator

The Scientific Notebook Coordinator is responsible for issuing scientific notebooks, overseeing the initial entry process, coordinating technical and compliance reviews thereof, and updating LBNL information in the centralized OSTI-LBNL Scientific Notebook Register in compliance with OSTI-LBNL-SIII.0, *Scientific Notebooks*.

3.5.7 Records Coordinator

The Records Coordinator is responsible for coordinating the submittal of all applicable records developed under the OSTI-LBNL QA Program to the RPC in accordance with OSTI-LBNL-17.0, and for providing for controlled distribution of OSTI-LBNL TWPs, QIPs, TIPs, and other documents that prescribe quality-affecting activities in accordance with OSTI-LBNL-6.0, *Document Control*.

3.5.8 Measuring and Test Equipment Coordinator

The Measuring and Test Equipment (M&TE) Coordinator is responsible for preparing and maintaining an up-to-date list of M&TE, coordinating internal and vendor calibration services, overseeing all other M&TE processes in accordance with OSTI-LBNL-QIP-12.0, *Control of Measuring and Test Equipment and Calibration Standards*, and maintaining and submitting all associated records thereof.

A single individual within the NWP QA technical support staff may be responsible for more than one of the coordinator responsibilities described above. QA functions also include numerous other activities such as preparation of planning documents, checking of technical documents, production of technical work products, coordination of document reviews, etc. which are assigned to qualified staff members, as needed, to assist scientific staff in meeting all requirements of the OSTI-LBNL Project.

3.6 Line Management Technical Personnel

Technical personnel include Research Area Leaders (RALs), PIs, and Scientific Staff. As depicted in Attachment 1, technical work performed by LBNL on the OSTI-LBNL Project is divided into research areas of expertise. The hierarchy suggested in the organization chart conveys levels of responsibility. All LBNL individuals performing technical work on the OSTI-LBNL Project report directly to the PM, Deputy PM, or designated PI.

Scientific personnel are responsible for carrying out assigned OSTI-LBNL tasks and satisfying all technical and quality requirements including those specified in contracts, purchase documents, or management directives. Scientific staff, together with OSTI-

LBNL QA technical support staff, are responsible for identifying problems relating to quality and for working with other scientific/QA personnel to define and implement solutions to problems.

3.6.1 Research Area Leaders

RALs are experts in their research area who serve as the point of contact for associated internal and external inquiries, and are responsible for coordinating/developing research interests/activities that are categorized by their common nature (e.g., ambient field testing, thermal testing, modeling) across departments within ESD. RALs serve as informal advisors to the PM on topics in these areas and may represent LBNL, as the PM's designee, on committees pertaining to their areas of expertise. In some instances RALs may also be PIs. In these instances, the RAL technical and quality responsibilities would be the same as that of a PI.

3.6.2 Principal Investigators

PIs report to the PM and are responsible for managing the technical work of their projects and ensuring that it is carried out in a technically defensible and cost-effective manner under sound QA practices. A PI may work alone on a project, but more commonly is supported by a number of scientific staff that are assigned to various project tasks. PI responsibilities include but are not limited to:

- A. establishing the quality standards for their projects/activities in compliance with the OSTI-LBNL QA Program and supplementary OSTI-LBNL QA procedure requirements;
- B. assuring that plans, TIPs, scientific notebooks, software, and/or other appropriate documentation are developed, approved, and followed for applicable quality-affecting activities;
- C. assuring implementation of quality requirements and providing supplementary training for applicable quality-affecting activities;
- D. assuring that applicable OSTI-LBNL TWP, and OSTI-LBNL QA implementing procedures are included in appropriate requests for proposals, bids, contracts, subcontracts, and purchase orders.

3.6.3 Scientific Staff

Scientific staff report to their assigned PI and are responsible for conducting their activities on the OSTI-LBNL Project in a technically defensible and cost-effective manner that includes compliance with the OSTI-LBNL TWP and OSTI-LBNL QA implementing procedures (i.e., QIPs, TIPs).

3.6.4 Contractors

All organizations that support or perform OSTI-LBNL quality-affecting activities, shall comply with the requirements of the OCRWM QARD and any applicable OSTI-LBNL QA Program documents or another OQA approved QA program meeting the QARD as specified by written agreement. Written agreements shall be used to document interfaces between such outside organizations and the OSTI-LBNL Project.

3.7 Training Requirements

OSTI-LBNL personnel who conduct activities subject to DOE/RW-0333P QARD requirements shall be trained in the applicable OSTI-LBNL-QA Program Documents as deemed appropriate by the Deputy PM, together with the PI and QA Manager.

4. RECORDS

The records listed in Section in 4.1 shall be collected and submitted to the RPC in accordance with OSTI-LBNL-QIP-17.0, as individual records or included in a records package.

4.1 QA Records

Delegation of authority

4.2 Non-QA Long Term Records

None

4.2 Non-QA Short-Term Records (Three years or less retention)

None

5. RESPONSIBILITIES

The overall responsibilities of OSTI-LBNL staff and interface with DOE/OQA are as described in Section 3 of this procedure.

6. ACRONYMS AND DEFINITIONS

6.1 Acronyms

CAQ	Condition Adverse to Quality
DOE	U.S. Department of Energy
ESD	Earth Sciences Division
LBNL	Lawrence Berkeley National Laboratory
M&TE	Measuring and Test Equipment
NWP	Nuclear Waste Program

OCRWM	Office of Civilian Radioactive Waste Management
OQA	Office of Quality Assurance
OSTI	Office of Science & Technology and International
PI	Principal Investigator
PM	Project Manager
QA	Quality Assurance
QARD	Quality Assurance Requirements and Description
QIP	Quality Implementing Procedure
RAL	Research Area Leader
RPC	Records Processing Center
TDMS	Technical Data Management System
TIP	Technical Implementing Procedure
TWP	Technical Work Plan

6.2 Definitions

None.

7. REFERENCES

DOE/RW-0333P, *Quality Assurance Requirements and Description*

OSTI-LBNL-QIP-2.0, *Indoctrination and Training of Personnel*

OSTI-LBNL-QIP-2.1, *Establishment and Verification of Required Education and Experience of Personnel*

OSTI-LBNL-QIP-2.3, *Surveillances*

OSTI-LBNL-QIP-4.0, *Procurement Document Control*

OSTI-LBNL-QIP-5.0, *Preparing the Quality Assurance Plan and Quality/Technical Implementing Procedures*

OSTI-LBNL-QIP-6.0, *Document Control*

OSTI-LBNL-QIP-6.1, *Document Review*

OSTI-LBNL-QIP-7.0, *Control of Purchased Services*

OSTI-LBNL-QIP-12.0, *Control of Measuring and Test Equipment and Calibration Standards*

OSTI-LBNL-QIP-17.0, *Records Management*

OSTI-LBNL-QIP-SI.0, *Software Management*

OSTI-LBNL-QIP-SIII.0, *Scientific Notebooks*

OSTI-LBNL-QIP-SIII.3, *Submittal and Incorporation of Data to the Technical Data Management System*

8. ATTACHMENTS

Attachment 1 - OSTI-LBNL Organizational Structure

9. REVISION HISTORY

04/01/04 Revision 0, Modification 0
Initial issue.

04/21/04 Revision 0, Modification 1
Included QA technical support positions described in text into the OSTI-LBNL Organization Chart; deleted Project Control Coordinator position. Changed acronym “OS&TI” to “OSTI.” Updated title for OSTI-LBNL-QIP-5.0.

10. APPROVALS

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OSTI-LBNL Project Organization

